



DEC 28 2009

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510(k) Summary
AUTION MAX AX-4030 Urinalysis System
Summary of Safety and Effectiveness Information
Supporting a Substantially Equivalent Determination

Submitter Name: ARKRAY, Inc.
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Kyoto, JAPAN 601-8045
TEL: (+81) 75-672-5311
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Contact Name: KENNETH L. BLOCK, RAC

Data Prepared: August 20, 2009

Proprietary Name: AUTION MAX AX-4030 Urinalysis System
Primary Product Code: KQO, JIL, JIO
Common Name: Urinalysis System
Class: I, II
CFR Section: 21 CFR 862.2900, 21 CFR 862.1340, 21 CFR 864-6650

Predicate Devices: K013783 AUTION MAX AX-4280 Urinalysis System
(ARKRAY, Inc.)

Device Description:

The AX-4030 device is composed of one main unit. A power cord provides the necessary electricity to run both the device and all of its components. The device is powered by the power cord which, itself, provides 100-200/200-240VAC with a frequency of 50-60Hz. The front of the main unit includes the LCD display screen and operator panel (top-center). In addition, there are several other features located along the bottom of the device including loading and unloading sides for urine samples. One of the best features that the AX-4030 includes is a built-in printer that is located on top of the device.

Indication for Use:

The AX-4030 is an automated urine analyzer that is designed to measure and analyze urine samples using measurements that include but are not limited to; Normal, STAT, Control and Check. These measurements are used to examine the following analytes; glucose(GLU), protein(PRO), bilirubin(BIL), urobilinogen (URO), pH (PH), blood (BLD), ketones (KET),

nitrite (NIT) leukocytes (LEU) and specific gravity (S.G.). In addition, this device is used only with AUTION Sticks 9EB multi-parameter test strips.

Cited Standards to Determine Substantial Equivalence:

AZ-4030 complies with UL 61010-1, CSA C22.2 No. 61010-1, IEC61010-1, IEC61010-2-101, IEC61010-2-081, EN61010-1, EN61010-2-101, EN61010-2-081, EN 61326, EN61000-3-2, EN 61000-3-3, JIS C 1806-1, JIS C 61000-3-2, and FCC Part 15 Subpart B.

Non-Clinical Testing:

Non-clinical verification and validation testing was conducted on the AX-4030 device and the results of such testing appear in Section 18 of this submission.

Software Validation:

AX-4030 software was validated in accordance with the appropriate FDA guidance documents and the required documents regarding all software design, development, risk analysis, and validation activities appear in Section 16 of this submission.

Truthful and Accuracy Statement:

Signed by a corporate management representative of the submitter, the required statement attesting to the truthfulness and accuracy of the information contained in Section 6 of this submission.

Further Information:

Please contact the following individual to request any further information regarding this submission:

Kenneth L. Block, RAC
Consultant
Ken Block Consulting
1201 Richardson Dr.
Suite 140
Richardson, TX 75080
TEL: 972-480-9554
FAX: 972-767-4325
Email: ken@kenblockconsulting.com



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

DEC 23 2009

ARKRAY, Inc.
C/O Mr. Kenneth L. Block
Ken Block Consulting
1201 Richardson Drive, Suite 140
Richardson, Texas 75080

Re: k093098

Trade/Device Name: AUTION MAX AX-4030 Urinalysis System
Regulation Number: 21 CFR 862.1340
Regulation Name: Urinary glucose (nonquantitative) test system
Regulatory Class: Class II
Product Code: JIL, KQO, CDM, CEN, JIN, JIO, JIR, JJB, JMT, JRE, LJX
Dated: December 1, 2009
Received: December 2, 2009

Dear Mr. Block:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K093098

Device Name: AUTION MAX AX-4030 Urinalysis System

Indications for Use:

The AUTION MAX AX-4030 Urinalysis System (AUTION MAX) is an automated urine analyzer intended for the in vitro measurement of the following analytes: glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrite, leukocytes, specific gravity, turbidity, and color. The AUTION MAX is intended for use only with AUTION Sticks 9EB multi-parameter test strips.

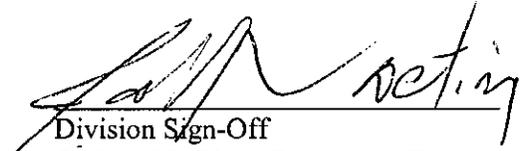
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K093098